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510(K) SUMMARY

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**
   Advanced Diagnostics Incorporated
   2400 Stevens Drive Suite C
   Richland, WA 99352
   Contact Person:
   Steve Hesler
   Manager of Regulatory Affairs
   509/ 375-4029
   Date Prepared:
   November 13, 2000
2. **Proprietary Name:**
   OS-2000 Optical Sonography System
   Common/ Usual Name:
   Diagnostic Ultrasound System
   Classification Name:
   Ultrasonic Pulsed Echo Imaging System (Product Code 90 IYO, 21 CFR 892.1560)
3. **Predicate Device:**
   The OS-2000 is substantially equivalent to a pre-amendment device, the Holoscope manufactured by Holosonics Inc. f Richland, WA.
4. **Device Description:**
   The OS-2000 is a general purpose, software-controlled, diagnostic ultrasound system that complies with pre-amendment application-specific acoustic output levels (track 1). Its function is to acquire ultrasound data in acoustical holography mode and display it on a CRT.
   The OS-2000 will meet the following product safety standards at the time it is released for distribution:

- UL 2601 – Standard for Medical Electrical Equipment - Part 1: General Requirements for Safety
- Performance Standards for Electronic Products, 21 CFR 1010.
- "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", September 30, 1997.
- "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices", CDRH, 1985.

5. **Intended Uses:**
The OS-2000 ultrasound imaging system is intended for the following uses: Small Parts, Pediatrics, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

6. **Technological Comparison to Predicate Device:**
OS-2000 is similar to the predicate device in that both use transmitted ultrasound and acoustical holography technology to generate images. Both the OS-2000 and the Holoscope utilize an object transducer that is coupled to the patient by use of a water-path (immersion in water bath or use of water bladders) to transmit pulsed ultrasound through the targeted tissues. These transmitted pulses are then acoustically focused. The focused ultrasound beam is then combined with a second plane wave (reference wave) of the same frequency as the transmit wave. The interaction of the transmit wave and the reference wave creates an interference pattern on a target detector device within the enclosed system, forming an acoustic hologram of the object. The detector is illuminated with a coherent light source (laser) resulting in a visual image. The visual image is recorded with a CCD video camera and the images are displayed on a video monitor. Images may be stored to hard disk.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2000

Steve Hesler
Manager of Regulatory Affairs
Advanced Diagnostics, Incorporated
2400 Stevens Drive, Suite C
Richland, WA 99352

Re: K001510
OS-2000 Optical Sonography Imaging System (Acoustic Holography Diagnostic Imaging System)
Unclassified
Procode: 90 NCS
Dated: September 15, 2000
Received: September 19, 2000

Dear Mr. Hesler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **OS-2000 Optical Sonography System**

Intended Use: Diagnostic ultrasound imaging of human soft tissues

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Acoustic Holography
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Neurosurgical										
Pediatric										N
Small Organ (Specify)										N**
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										N
Laparoscopic										
Musculo-skeletal Conventional										N
Musculo-skeletal Superficial										N
Other (specify)										

N = new indication; **P = previously cleared by FDA;** **E = added under Appendix E**

Other Indications or Modes: ****Small parts imaging is intended for the breast**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001510